Versa
POSITIONING SOLUTIONS

INSTRUCTION MANUAL

Man.Ver. EN Rev.4 04/2025

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ProMedicare®

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NOTE: The Illustrations in the following Instruction Manual may differ from reality; however, the methods of use and operation remain valid at all times. All technical data in this manual are approximate and do not constitute specifications.

NTRODUCTION

Dear User, thank you for choosing highly performing Pro Medicare medical device.
The *VERSA* Range is the combination of technology and experience in the development of Positioning Systems for users with limited ability. Thanks to its modularity and different possibilities of adjustment, the Positioning system allows effective adaptation to changes of the user's needs; *VERSA* Positioning System, combined with ADACTA Frame for Positioning System (manufactured by Pro Medicare) or other manufacturer Frame for Positioning System, will provide the best comfort with maximum functionality.
As manufacturer, Pro Medicare declares that the medical device complies with Regulation (EU) 2017/745. Pro Medicare's Quality Management System is certified according to UNI EN ISO 9001 and UNI EN ISO 13485 standards.
This manual, drawn up on the basis of the requirements of Regulation (EU) 2017/745 on medical devices, is an indispensable tool for learning how to use the Device safely.
This manual contains all instructions for a correct and safe use of the Positioning System combined with Frame for Positioning system or its accessories. To this end, it is important to read the information about how to use it carefully, with the express invitation to follow the prescribed indications.
As a manufacturer, Pro Medicare refers to the *Professional User* as the suitably qualified person (authorised dealer, orthopaedic technician, occupational therapist, healthcare professional, etc.), and to the *End User* (*or lay person*) as the person who is intended to use the Device (caregivers, family members, etc.).

The first commissioning, subsequent adjustments and Special Maintenance must exclusively be performed by the Professional User.

The Technical features of the device are reported in the Annex A "Technical Features".
After consulting this manual, for further information, please contact the Technical Sales Department at the number **+39 0831 777840**, Monday to Friday from 9 a.m. to 1 p.m. and from 2.30 p.m. to 6.30 p.m.
In case of emergencies outside the working hours, please send an email to: **sales@promedicare.it**.
We will call you back as soon as possible.
In order to ensure appropriate After-Sale Monitoring of Devices placed on the market and put into service, or in the event of an incident during the use, please refer to the instructions stated in the relevant chapter.

USE

All the *VERSA* Range Positioning Systems have been designed and manufactured in compliance with the safety standards of Regulation (EU) 2017/745.
VERSA Range Devices are intended to be used by non ambulatory users with limited ability who are forced to sit, suffer from postural insufficiency and with various diseases, such as, for example, ICP, muscular dystrophy, multiple sclerosis, amyotrophic lateral sclerosis, head injury, spinal cord injury and stroke.
VERSA is synonymous with customization. Its seats, backrests and accessories are individually designed, manufactured and combined. With *VERSA* the Positioning System becomes a tailor-made suit that fits perfectly. Accuracy in realization, which begins with the detection of the user's body measurements, from the position tests on the Simula, is completed with the choice of materials, shapes and forms in a totally modular and constantly evolving technology. The *VERSA* System thanks to its materials, its construction features and various types of hardware, accompanies the user, performing for many years.
The Professional User is the responsible for the safety performance in compliance with the Standards of the Frame for Positioning System and the Positioning System combination.
The first commissioning, subsequent adjustments and Special Maintenance must exclusively be performed by the Professional User.
Pro Medicare is constantly dedicated to innovate its own Devices; This can entail changes in form or technique on the devices and/or related accessories. Therefore, hypothetical complaints on values, images and schemes defined in the this manual, will not be accepted. Furthermore, for the complete list of the optional parts and/or accessories, please refer to the latest order form in force.

1. INSTRUCTIONS OF USE

1.1 Packaging and Transport

The original packaging contains the following components:

- the posititioning system and/or related accessories
- mounting screws
- labeling and instruction of use.

Upon delivery, please check for the integrity of the package and immediately note any damages or anomalies on the shipping document. Then open up the packaging and check that the various parts do not show dents, drippings, deformations or tears. Otherwise note the anomalies found on the shipping document.
After performing these checks and if the product has not to be put into immediate use, we recommend to repack and store it in a dry place.
The above operation will be carried out by the Professional User who has to perform the assembling procedures of the Frame for Positioning System with the Positioning System.

1.2 Preliminary Operations for correct Commissioning

If the Frame for Positioning System is used in combination with the *VERSA* Positioning System, it must have the following technical features:

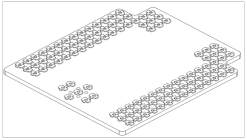
- the base must have a tubular structure with a diameter of 20, 22 or 25 mm. If the base has square tubes, installation will always be possible using an adaptability kit
- the base must be stable enough to support the user on its positioning system, ensuring safety in all conditions.

The professional user and the end user need to check that the frame/posture connection system is safely manufactured.

1.3 Combination of VERSA Positioning System and the Frame for Positioning System

These operations must exclusively be performed by the Professional User, who is responsible for the safety performance of the combination and/or configuration.

All the *VERSA* Range Positioning Systems are made of a wooden or plastic base equipped with threaded inserts (see example in fig. 1), to be used for the installation of the device itself on the wheelchair or its anchoring system. The positioning of the holes on the device allows the proper adaptation of the end user.



***pic. 1**: base with threaded inserts*

1.3.A *VERSA* combination with other manufacturer frames for positioning system

The seat and the backrest are anchored to the longitudinal tubes of the frame with specific clamps fixed to slotted plates. The slot allows the sliding of the structure (plate + clamp) facilitating the correct positioning of both the seat and the backrest. The company supplies the seat and backrest without the clamps and plates since the width of the base to which the *VERSA* positioning systems have to be mounted is not known. The Professional user has the responsibility to determine the correct position of the clamps through the following operations in order to make the combination of the seating system with the base secure.

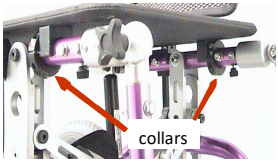
a) Seat positioning

Insert the two screws inside the slot and screw them without tightening them into the rows of holes on the seat base by punching the cover (pic. 2).
In this way the whole structure (clamp + plate) slide along the slot, therefore it is possible to determine the position on tubes where they should be fixed. The sliding along the slots allows to adjust the width of the seat position. When adjusting the width of the seat, take care to accurately center the seat and then fix it; please, perform this operation as follows:
- place the seat on the tubes and let the plates to slide freely
- slide the whole structure along the slots until the seat is centrally positioned
- tighten the screws and lock the position.

***pic. 2**: seat positioning*

b) Seat fixing

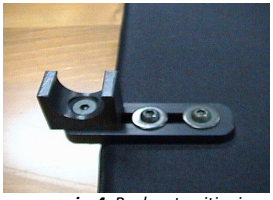
Place the seat on the relevant tubes of the base. Pay attention to the 2 front clamps placed under the seat; for a correct installation they have to be positioned in contact and alternatively, one in front and one behind the relevant collars fixed on the tubes (pic. 3). This prevents the seat from sliding back and forth. Once correctly positioned, press firmly the seat towards the tubes until you will hear the click indicating the engagement of the 4 clamps of the seat on the tubes.
Check the seat is properly assembled into position:
- move it back and forth along the guide tubes of the wheelchair
- move it upwards.
With these operations the seat must not be able to move.



***pic. 3**: seat fixing*

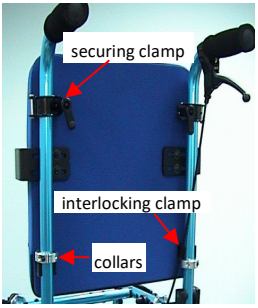
c) Backrest positioning

Insert the two screws inside the slot and screw them without tightening them into the rows of holes on the backrest base by punching the cover (pic. 4). In this way the whole structure (clamp + plate) slide along the slot, therefore it is possible to determine the position on tubes where they should be fixed. The sliding along the slots allows to adjust the width of the backrest position. When adjusting the width of the backrest, take care to accurately center the backrest and then fix it; please, perform this operation as follows:
- place the backrest on the tubes and let the plates to slide freely
- slide the whole structure along the slots until the backrest is centrally positioned
- tighten the screws and lock the position.


***pic. 4**: Backrest poitioning*

d) Backrest fixing

The rear part of the backrest has 4 clamps fixed; the 2 interlocking clamps are at the bottom like those of the seat, the other 2 at the top are secured by tightening the plastic knob. Place the backrest on the relevant tubes of the base taking care to position the tubes in the appropriate seats of the clamps. Press the lower part of the backrest towards the tubes until you hear the click to indicate the engagement of the 2 lower clamps. For a correct installation they have to be positioned in contact and alternatively, one above and one below the relevant collars fixed on the tubes (pic. 5). This prevents the backrest from sliding up and down. Then lock the 2 upper clamps by tightening the appropriate knobs.
Check the backrest is properly assembled into position:
- move it up and down along the backrest tubes
- move it outwards.
With these operations the backrest must not be able to move.



***pic. 5**: backrest fixing*

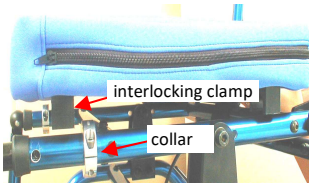
⚠ *After all these operations please ensure that the frame combined with the positioning system is secure, moves easily and all components work properly. If you hear noise, vibrations or if there are any changes to the normal conditions of use, please contact the Professional User; He will check the safety conditions, the suitability for use and the effectiveness of the Device.*

1.3.B *VERSA* and ADACTA Frame for Positioning System Combination

To combine the *VERSA* Positioning System with the *Adacta* Frame for Positioning System (manufactured by Pro Medicare) please perform as follows:

a) Seat fixing

The rear part of the seat has four interlocking and/or securing clamps that allow it to be mounted on tubes. Place the seat on the relevant tubes of the base. Pay attention to the 2 front clamps placed under the seat; for a correct installation they have to be positioned in contact and alternatively, one in front and one behind the relevant collars fixed on the tubes (pic. 6). This prevents the seat from sliding back and forth. Once correctly positioned, press firmly the seat towards the tubes until you will hear the click indicating the engagement of the 4 clamps of the seat on the tubes or in case of securing clamps, tighten them on the tubes once positioned.
Check the seat is properly assembled into position:
- move it back and forth along the guide tubes of the wheelchair
- move it upwards.
With these operations the seat must not be able to move.

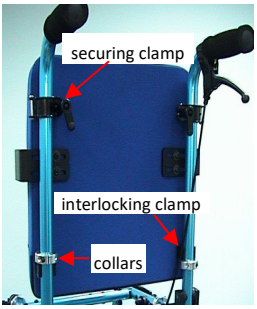


***pic. 6**: seat fixing*

b) Backrest fixing

The rear part of the backrest has 4 clamps fixed; the 2 interlocking clamps are at the bottom like those of the seat, the other 2 at the top are secured by tightening the plastic knob.
Place the backrest on the relevant tubes of the base taking care to position the tubes in the appropriate seats of the clamps. Press the lower part of the backrest towards the tubes until you hear the click to indicate the engagement of the 2 lower clamps. For a correct installation they have to be positioned in contact and alternatively, one above and one below the relevant collars fixed on the tubes (pic. 7). This prevents the backrest from sliding up and down. Then lock the 2 upper clamps by tightening the appropriate knobs.
Check the backrest is properly assembled into position:
- move it up and down along the backrest tubes
- move it outwards.

With these operations the backrest must not be able to move.



***pic. 7**: backrest fixing*

After all these operations please ensure that the frame combined with the positioning system is secure, moves easily and all components work properly. If you hear noise, vibrations or if there are any changes to the normal conditions of use, please contact the Professional User; He will check the safety conditions, the suitability for use and the effectiveness of the Device.

1.3.C Posture support Accessories fixing

If there are any posture support Accessories, they are provided separately to the positioning system. In paricular, thoracic supports and hip guides are mounted using screws and slotted brackets that must be installed respectively on the backrest and on the seat according to the instructions of the professional user. The seat and backrest have rows of holes with threaded inserts along the edges to insert the locking screws of the brackets.

After all these operations please ensure that the frame combined with the positioning system is secure, moves easily and all components work properly. If you hear noise, vibrations or if there are any changes to the normal conditions of use, please contact the Professional User; He will check the safety conditions, the suitability for use and the effectiveness of the Device.

1.4 Adjustments for the first Commissioning and/or subsequent adjustments

The configuration of the positioning system perfectly accommodates the user if the device has been correctly identified and ordered. Any changes for commissioning or periodic adjustments due to end-user's changing needs are possible, as the system is designed and manufactured to allow a various number of adjustment possibilities. The user can be seated on the positioning system when all the support accessories adjustments of have been performed. This section describes the adjustment of these accessories.

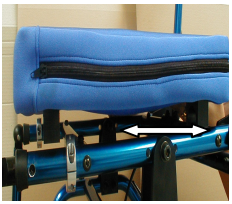
These operations must exclusively be performed by the Professional User.

a) Seat

Seat depth and width can be adjusted gradually and independently

√ Depth adjustment

The seat is mounted on the base using 4 clamps and two collars fixed on the base tubes prevent it from sliding. The collars are in contact and alternatively, one in front and one behind the front clamps. Depth adjustment is performed as follows (pic. 8):
- unscrew and loosen the fixing screws of the collars placed on the base tubes
- slide the seat along the tubes to the desired position
- re-tighten the fixing screws of the collars.


***pic. 8**: depth adjustment*

It may also be necessary to move the clamps along the edge of the seat. In this case, perform as follows:

- *VERSA* adjustment on other manufacturer wheelchair base:
  1. unscrew and remove the countersunk screw that secure the slotted bracket
  2. slide the slotted bracket along the edge of the seat to the desired position and in relation to the holes along the edge of the seat (spacing of 2.5 cm)
  3. drill the cover, insert and secure the countersunk screw

- *VERSA* adjustment on ADACTA wheelchair base:
  1. unscrew and remove the countersunk screw that blocks the clamps
  2. slide the clamp along the edge of the seat to the desired position and in relation to the holes along the edge of the seat (spacing of 2.5 cm)
  3. drill the cover, insert and secure the countersunk screw.

Make sure the collars are placed alternatively one in front and one behind the clamps to prevent the seat from sliding forward.

√ Width adjustment

The seat width is performed by moving possible lateral hip guides which are fixed to slotted brackets. Brackets, are mounted under the seat (pic. 9):
- unscrew and loosen the button head screws wich fix the bracket to the seat
- slide the hip giude inward or outward the seat to the desired position
- tighten and fix the button head screws.

It may be necessary that the screws must engage rows of adjacent holes to move the bracket.

***pic. 9**: width adjustment*

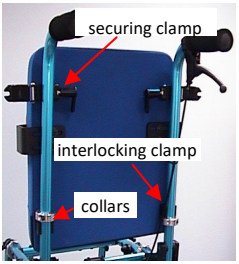
It is advisable not to fasten the pelvic belt to the seat.

b) Backrest

Backrest width and height can be adjusted gradually and independently

√ Height adjustment

The backrest is mounted on tubes using 4 clamps. Both the two collars mounted on tubes wich are in contact with the 2 interlocking clamps and the 2 securing clamps, prevent the backrest from sliding. The height adjustment is performed as follows (pic. 10):
- unscrew and loosen the fixing screws of the collars
- unscrew the knobs of the securing clamps
- slide the backrest on tubes to the desired position
- tighten the fixing screws of the collars
- tighten the knobs of the securing clamps.



***pic. 10**: height adjustment*

It may also be necessary to move the clamps along the edge of the backrest.
In this case, perform as follows:

- *VERSA* adjustment on other manufacturer wheelchair base:
  1. unscrew and remove the countersunk screw that secure the slotted bracket
  2. slide the slotted bracket along the edge of the backrest to the desired position and in relation to the holes along the edge
  3. drill the cover, insert and secure the countersunk screw.
- *VERSA* adjustment on ADACTA wheelchair base:
  1. unscrew and remove the countersunk/button head screw that blocks the interlocking/securing clamp
  2. slide the clamp along the edge of the backrest to the desired position and in relation to the holes along the edge
  3. drill the cover, insert and secure the countersunk screw.

Make sure that the collars are placed alternately one below and one above the clamps to prevent the backrest from sliding.

√ Width adjustment

The backrest width is performed by moving possible thoracic supports which are fixed to slotted brackets. Brackets are mounted under the backrest (pic. 11):
- unscrew and loosen the button head screws wich fix the bracket to the backrest
- slide the thoracic support inward or outward the bakrest to the desired position
- tighten and fix the button head screws.

It may be necessary that the screws must engage rows of adjacent holes to move the bracket

***pic. 11**: width adjustment*

c) Arm supports

Arm supports and whichever shape of them is chosen, are fixed to the hip guides by means of 2 slotted L brackets present rows of threaded holes in order to allow a wide range of adjustments, such as, height and angle, width and intra-extra rotation and depth.

√ Height adjustment (pic. 12)

- unscrew and loosen the button head screws of the brackets fixed to the lateral support
- slide the arm support down or up or tilt it to the desired position
- tighten and fix the button head screws.

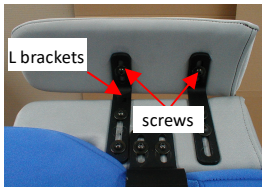
√ Width adjustment (pic. 13)

- unscrew and loosen the button head screws of the brackets fixed to the arm support
- slide the arm support inward or outward or tilt it to the desired position
- tighten and fix the button head screws.

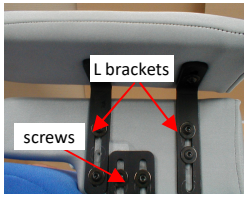
√ Depth adjustment (pic. 14)

- unscrew and remove the button head screws of the brackets fixed to the lateral support
- move the arm support forward and backward along the lateral support to the desired position and in relation to the rows of holes of the lateral support
- drill the cover, insert and secure the button head screws.

pic. 12: *height adjustment*



pic. 13: *width adjustment*

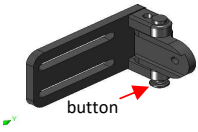


pic. 14: *depth adjustment*

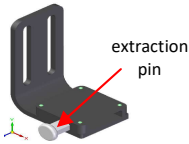
If the patient has dyskinesias and involuntary movements of the limbs, the company manufactures supportive restraints for upper and lower limbs upon notice to the technical sales department.

d) Thoracic supports

The thoracic support can be fixed to the backrest with a bracket or with a detachable (pic. 16) or folding mechanism (pic. 15). The bracket to which the thoracic support is fixed can be of various types and depends on the thoracic width of the end-user. The folding mechanism has a colored button, if activated it allows the opening of the pad; the detachable mechanism has an extraction pin, if rotated and pulled it allows the extraction of the whole thoracic support including the pad; it is recommended to mount the two mechanisms with button/pin facing downwards. The thoracic supports can be also positioned at different heights and can be adjusted in depth, width and angle. They have rows of holes with threaded inserts to allow a wide range of adjustments.



pic. 15: *folding mechanism*



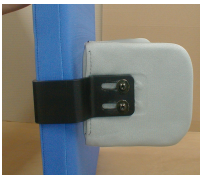
pic. 16: *detachable mechanism*

√ Height adjustment (pic. 17)

- unscrew and remove the button head screws wich fix the bracket to the backrest
- move the thoracic support up or down along the edge of the backrest to the desired position and in relation to the rows of holes on the edge
- drill the cover, insert and secure the button head screws.

pic. 17: *height adjustment*

√ Depth and anle adjustment (pic. 18)
- unscrew and loosen the button head screws wich fix the thoracic support to the bracket
- slide the bracket inward and outward or angle it to the desired position
- tighten and fix the button head screws.
It may be necessary that the screws must engage rows of adjacent holes for greater thoracic support movement.


pic. 18: *depth adjustment*

e) Hip guides

The hip guides are fixed to the seat by brackets or with a detachable mechanism; the detachable mechanism has an extraction pin, if rotated and pulled it allows the extraction of the whole hip guide including the pad.
The distance between the two hip guides determines the width of the seat. The Hip Guides can be also adjusted in depth, height, width and abduction/adduction. They have rows of holes with threaded inserts to allow a wide range of adjustments:

√ Depth adjustment
(option 1) (pic. 19) by operating on the button head screws of the bracket, located beneath the seat:
- unscrew and remove such screws
- move the hip guide back and forth along the edge of the seat base to the desired position and in relation to the rows of holes on the edge
- drill the cover, insert and secure the button head screws.


pic. 19: *depth adjustment - opt.1*

(option 2) ((pic. 20) by operating on the button head screws connecting the bracket to the hip guide:
- unscrew and loosen such screws
- slide the hip guide back and forth to the desired position and in relation to the rows of holes on the same hip guide
- drill the cover, insert and secure the button head screws.
It may be necessary that the screws must engage rows of adjacent holes for greater hip guides movement.


pic. 20: *depth adjustment - opt.2*

√ Height adjustment (pic. 21)
- unscrew and loosen the button head screws fixing the hip guide to the bracket
- move the hip guide up and down to the desired position
- retighten and fix the button head screws.
It may be necessary that the screws must engage rows of adjacent holes for greater hip guides movement.


pic. 21: *height adjustment*

√ Width adjustment (pic. 22)
Width adjustment is performed by operating on the button head screws of the bracket, located beneath the seat:
- unscrew and remove such screws
- slide the hip guide inward or outward the seat width to the desired position and in relation to the rows of holes under the seat base
- drill the cover, insert and secure the button head screws.
It may be necessary that the screws must engage rows of adjacent holes for greater bracket movement.


pic. 22: *width adjustment*

√ Abduction/adduction adjustment
Abduction/adduction adjustment is performed as follows:
- unscrew and loosen the button head screws wich fix the seat to the bracket
- adjust the hip guide to the desired position
- retighten the button head screws.
It may be necessary that the screws must engage rows of adjacent holes for greater bracket movement.

f) Abductor wedge

The Abductor Wedge, which can be removed with lever or block, is mounted to an L shaped Bracket and it is locked under the seat with a clamping knob.

√ Abductor Wedge removal
- unscrew and loosen the clamping knob
- slide the bracket.

√ Abductor Wedge inserting
- place the bracket under the seat, taking care to slide the slot along the button head screws
- screw the clamping knob
- verify the right inserting by checking the impossibility of movement.

√ Height adjustment (pic. 23)
- unscrew and loosen the Abductor Wedge fixing button head screws to the bracket
- slide the abductor wedge up and down to the desired position
- tighten and fix the button head screws.

pic. 23: *height adjustment*

√ Abductor Wedge lateral adjustment (pic. 24)

The abductor wedge can be mounted laterally in relation to the rows of holes located under the wooden base along the front edge. For the adjustment, please perform as follows:
- unscrew the fixing button head screw
- slide the bracket to the right or left and in relation to the rows of holes as shown in the picture, until the desired position is achieved
- drill the cover, insert and fix the button head screw
- insert the clamping knob. For correct functionality, the knob needs to be be positioned behind the button head screw.

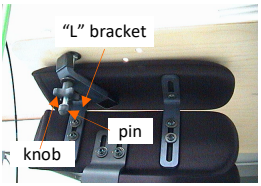
pic. 24: *Abductor Wedge lateral adjustment*

g) Tray

Any shape of tray can be fixed to the armrests or arm supports by detachable or lateral flip mechanism. It is secured as follows:

(option 1) detachable mechanism (pic. 25)
- verify that the fixing L brackets firmly grip the arm supports/armrests. In a contrary case, please remove the pin and move it a most suitable exagonal shaped hole onto the lateral edges of the tray
- strongly tighten the loching knob
- check the tray is stable.

If it is a tubular armrest, refer to pic. 26.



pic. 25: *detachable mechanism*

pic. 26: *tubular armrest mounting*

(option 2) Lateral flip mechanism (pic. 27)

The mounting can be done as follows: (the picture shows the hardware only):
- mount the guide tube with its clamping knob under the arm support
- insert the rod of the hardware in the guide tube
- tighten the knob firmly
- tigheten and fix the round head screws.

pic. 27: lateral flip mechanism

1.5 How to use it

The *VERSA* positioning system combined with the base, after the Professional User has performed the adjustment, is ready to be used. Following there are all modes of use. Before to start any operation the caregiver needs to be instructed by the professional user for correct commissioning. Practice all operations of daily use. It is advisable to develop one's own methods for safe use, appropriate to the needs.

During daily use it may happen that components and/or accessories become loosen, affecting adjustments, this is why it is recommended to schedule a follow-up to monitor and check the posture. Never make any adjustments or changes without the intervention of the Professional User.

a) *End-user transfer from/to the System*

Before performing these operations, it is important to inform the end user about the most natural and regular operations that needs to be done. This will help to make it easier for the user and it will reduce possible dangers.

Transfer from the System

√ Ensure the brakes are on, and the frame is locked from movements
√ Ensure the anti-tip device are correctly positioned
√ Loosen any fixing harness
√ Disengage any thoracic supports and folding and/or detachable hip guides to facilitate transfer and avoid trapings
√ Disengage footrests to reduce the danger of entrapment of feet during transfer.

Now the user is ready to be transferred. Please pay particolar attention to this operation.

Transfer to the System

√ Engage the brakes and make sure the frame is locked
√ Ensure the anti-tip device are correctly positioned
√ Lift and transfer the user to the system by paying particular attention to this operation
√ Engage any thoracic supports and folding and/or detachable hip guides
√ Position and adjust the footrest
√ Fasten any fixing components
√ Make sure that the user is in his normal seating position.

While the positioning operation is ongoing, ensure that no part of the body is trapped.

b) Transporting the system

For an easy transportation of the system, it is necessary to proceed with the removal of the Positioning System from the Frame by carefully following the steps below:

Pay particular attention to the following operations; do not lift the backrest by the thoracic supports and the seat by the armrests: they can become loose and change the configuration of the System. Lift only by the components that cannot be detached. Check that all adjustments have not been altered. If changes are noted, please contact the Professional User.

- Disassemble the Positioning System from the Frame for transportation in a vehicle

In order to transport the system in a vehicle, it is necessary to remove the Positioning System from the Wheelchair Base:

1) Apply the brakes ensuring the frame cannot move
2) Remove the seat: pull the seat upwards until it clicks, indicating that the 4 seat clamps are detached from their two relative tubes
3) Remove the backrest: the backrest has 4 clamps fixed in the rear part; the 2 clamps positioned at the bottom are interlocking like those of the seat, the other 2 positioned at the top are locked by tightening the plastic knob. Unscrew the 2 knobs until the clamps are released, remove the backrest from the backrest tubes by holding it at the bottom and push until you hear the click that indicates the detachment of the 2 lower clamps.
4) Make the frame base compact.
5) Now the seat, backrest and frame can be placed in a vehicle.

Subsequent start-up of the Frame and recombination of the Positioning System with the Frame

At the end of the trip, bring out the frame, the seat and the backrest from the vehicle and preoceed with the following operations:

1) Put the base into service
2) Apply the parking brake and make sure the frame doesn't move
3) Seat fixing: fix the seat on the base following the instructions on page 6 point b)
4) Backrest fixing: fix the backrest as shown on page 6 point d)

After having performed these operations make sure that the Frame combined with the Positioning System is stable, easy to move and that all components work in harmony. If you hear noise, vibrations or if there are any changes to the normal conditions of use, please contact the Professional User; He will check the safety conditions, the suitability for use and the effectiveness of the Device.

1.6 Recommendation for use

In order to guarantee safe use and a long lasting performance of the Frame for Positioning System, please find below advices for the end user:

√ Carefully follow the instructions reported in this manual
√ Follow the recommendations provided by the Professional User
√ Keep the Device away from heat sources
√ Avoid using the armrests as a support base for the user
√ Carry out thorough cleaning and pay close attention to the standard maintenance.

2. GENERAL WARNINGS

All announcements reported in this section describe the conditions and situations that may cause danger to the user or to third parties. Please read carefully before using and putting in service the System. To ensure the correct use of the Device, some operations, such as the first commissioning and adjustments, must only be performed by authorized people - *the Professional User* - Some daily operations can obviously be performed by the *End User* (or *lay person*). Therefore, there will be specific warnings for those concerned. In particular, the term *Professional User* describes the suitably qualified person (authorised dealer, orthopaedic technician, occupational therapist, healthcare professional, etc.), while, the term *End User* describes the person who is intended to use the Device (caregivers, family members, etc.).

2.1 Warnings for the Professional User

For further information, please contact the Technical Sales Department at the following number:

+39 0831 777840

- Preliminary Operations for correct Commissioning: (to be performed in accordance with the instructions provided in *sect. 1.2*)
  - After having performed these operations make sure that the Frame combined with the Positioning System is stable, easy to move and that all components work in harmony
  - Check for noise, vibrations or if there are any changes to the normal conditions of use to ensure the safety conditions and the suitability for use.

- Adjustment: (to be performed in accordance with the instructions provided in *section 1.4*)
  - These operations must be performed by authorized people
  - During these adjustments, the anti-tip castors must be positioned to reduce the risk of the System tipping
  - After having performed these adjustments, be aware of any noise, vibrations or any changes to the normal conditions of use to ensure the safety conditions and the suitability for use
  - Unauthorized modifications or the use of parts not supplied or approved by the manufacturer may affect the safe and operational integrity of the system and be cause of danger.

2.2 Warnings for the End User

Before using the Device ensure the Professional User explains the procedures for correct commissioning and standard maintenance. For further information, please contact the Professional User.

- Environmental Conditions

Severe environmental conditions may affect the features of the materials used, *VERSA* range positioning systems, the functionality and performance of the structure, so:

- Avoid the exposure to extreme temperatures
- Avoid prolonged exposure to sunlight

- Avoid extreme humid places (for example: do not bring the wheelchair into a steamy bathroom after a shower)
- Avoid contact with seawater
- If the wheelchair gets dirty dirt, please carry out an immediate and thorough clearing.

- Components and Options

Armerest. The armrests cannot support the weight of the wheelchair, if used for lifting the wheelchair, they may become damaged and can break.

- Use

- If you hear noise, vibrations or any abnormality after a few days of use, please contact the professional user.
- Be careful when moving the wheelchair over uneven ground or obstacles, which if in contact with wheels, they can cause the wheelchair to tilt.
- In the event that an accident causes a loss of performance, do not use the system and consult the professional user.
- In the case of a sudden deterioration in performance, do not use the system and consult the professional user.
- Never perform any adjustment or change without the intervention of the professional user.
- In case of malfunctions resulting from other causes, including poor maintenance of the wheelchair, the professional user should be consulted.
- For the cleaning operations do not use aggressive products which may affect the cover.
- Frequently check all the connections between the positioning system and the frame and verify for a safe and fully functional operations.

3. NEGATIVE ADVERSE EFFECTS

Generally the use of the positioning system should not cause any adver effects such as allergies, skin irritations or redness when in contact (the cover is latex-free, is at low risk of irritation to the skin and it is commonly used in medical devices). Otherwise, please contact both the Doctor and the Professional User immediately. Daily monitor the skin area which is in contact with the Device for evidence of pressure sores caused by incorrect or outdated adjustments; in this case it is suggested to suspend the use and contact the Professional User.

4. RESTRICTIONS OF USE

The Positioning System combined with the frame for positioning system has been designed and manufactured to provide the end user the correct positioning support within the normal activities of daily working life, social relations, school or leisure time. Any other use may compromise the safety of the Device.

Mandatory Requirements

- When the user is on board, avoid lifting the wheelchair by the legrests or any posture accessories. If it is necessary, lift the wheelchair by the sides of the base structure, making sure the seat assembly doesn't move during this operation.
- Get help from additional people when you have to lift the wheelchair over obstacles.
- All replacement parts or adjustments not authorized by the manufacturer are strictly forbidden.
- For safety, never leave the user alone in the wheelchair, especially in the case of children.

5. STANDARD MAINTENANCE

In order to guarantee a good functioning and long lasting performances in safe conditions it is necessary to check regularly and make periodically maintenance. This operation must be performed by the end user.
The regular maintenance consists of two parts: cleaning and mechanical parts checking.

- Cleaning -

The metal parts can be cleaned with a damp cloth with cold water without addition of detergent, taking care to go over everything with a dry cloth.
Regarding the cover of the positioning system accessories, even if there is no prolonged contact with the skin, it is recommended to perform a careful cleaning every two weeks in order to avoid the development of infections. Regarding the cleaning it is suggested to use a dump cloth or a brush with natural bristles and tepid water (max 30°C), with the addition of a light gentle detergent only; drying must be done away from heat sources.
If the seat and backrest cover is removable, it can be hand-washed with warm water (max 30°) and neutral detergent without bleach; if it is not removable, use a damp cloth or a brush with natural bristles and tepid water (max 30°C), with the addition of a light gentle detergent only; in both cases, drying must be done away from heat sources.

- *Mechanical Parts Checking* -

The following operations have to be performed:

* Monthly check the screws and their tightening mechanism.
* Check the adjustments: it is strictly recommended to respect the program of the checks and monitoring scheduled with the professional user.

6. ADAPTATIONS WITH STRUCTURAL CHANGES AND/OR SPECIAL MAINTENANCE

Special maintenance should be performed when one or more structural components deteriorate in such way to compromise the performance and safety of users. In this case do not use the Device and immediately contact the Professional User who shall promptly inform the manufacturer about the nature of the malfunction and/or the failures found in order to proceed with the necessary interventions. The instructions below must be followed at all times:

- Components failure such as clamps, guides and screws: they must be replaced with original parts provided by the manufacturer, restoring the original safety conditions.
- Breakages or tears of the linkage brackets of the hip guides and the seat and of the backrest: they must be replaced with original items provided by the manufacturer.
- Breakages or tears of the postural supports: they must be replaced with original items provided by the manufacturer. If the breakage or tear only affects the cover, only the cover will be replaced.
- For all structural components it is strictly forbidden to perform any repair and repair by welding, bolted or riveted joints.
- We recommend a gradual adaptation of the system to any user's needs.

The non observance of the above clauses will automatically void the CE mark.
For special maintenance, the End User must refer to the Professional User who has to send the appropriate form "*Annex 1 - Warranty Replacement, Adaptations with structural changes and/or special maintenance*" to the manufacturer within 24 hours of the request for intervention.

7. PERFORMANCE AND DURABILITY

Pro Medicare S.r.l. ensures that its own production of the *VERSA* range Positioning Systems have been designed and produced in compliance with the safety regulations as required by the relevant Regulation (EU) 2017/745.
The benefits provided by the above mentioned medical devices, either individually or in combination, are therefore suitable and respond to the project's purpose, which is the mobility of users with severe disabilities, considering a more effective rehabilitation plan based on correct posture and stability.
The realistic life span in safety conditions of the *VERSA* range Positioning Systems combined with frames manufactured by other companies or the Adacta Frames manufactured by Pro Medicare is approximately 3 years. These value is purely indicative because, even if the duration expected in the design phase is much greater, it is significantly determined by the way the device is used (which may be how it has been used and if it has been used continuously compared to what was intended in the design phase), by the correct use and careful maintenance.
It is also reasonable to consider a slight reduction in performance over time due exclusively to:

* shocks and accidental events
* natural wear of the components.

Both performance and relative life span expectancy are however dependent by the periodic verification of the suitability, combination safety and the right System adjustments and have to be exclusively performed by the Professional User.
Regular reassessment by the professional user should therefore be provided in order to check the suitability, safe and integrity of the system. If the Professional User deems it necessary, he can make adjustments to provide the right support and maintenance. The reconditioning of the device is prohibited if not expressly authorized by the manufacturer.

8. WARRANTY

Pro Medicare S.r.l. warrants the devices functionality for a maximum period of 24 months, covering all manufacturing defects from the first commissioning and 12 months on components and covers replaced under special maintenance starting from the date of commissioning after refurbishment.
The warranty is valid if the device is used as indicated within this instruction manual.
The warranty is voided in the following cases:

- improper use and/or in case of force majeure
- a failure arising from an unauthorized tampering or faulty maintenance by third party that compromises the correct functionality and safety of the products
- any modification made without the manufacturer's authorization
- accidental damages and wear of the essential components

- structural changes of the end user
- failure or damages during the transportation: the Professional User is pleased to refer to the general sales conditions
- stolen or loss.

For warranty replacement of components, the End User must refer to the Professional User who has to send the appropriate form "*Annex 1 - Warranty Replacement, Adaptations with structural changes and/or special maintenance"* to the manufacturer within 24 hours of the request of intervention. It is also essential for the manufacturer to receive a completed *Warranty Registration Form.*

9. POST-MARKET SURVEILLANCE AND POSSIBLE INCIDENTS

Pro Medicare S.r.l. ensures that their medical devices have been manufactured within the strict compliance, criteria and requirements established by the relevant applicable standards, guarantee functioning under the safety conditions prescribed by Regulation (EU) 2017/745. The post-market surveillance system is set up and implemented in accordance with the quality management system adopted by Pro Medicare S.r.l. and is aimed to actively and systematically collect, record and analyse relevant data on the quality, performance and safety of its devices during their whole life, to establish the necessary conclusions and to determine, implement and monitor any preventive and corrective actions (art. 83 MDR).
These activities are also ensured through accurate market surveillance of the medical devices already present on the market, as also included in Art. 84 of the same Regulation (EU)2017/745.
To ensure Post-Market Surveillance, Pro Medicare S.r.l. shall implement all activities together with Professionals and Stakeholders to establish and keep updated a systematic procedure which is useful to collect and promptly analyze the experience gained on devices that have been placed on market, in order to identify any need for improvement or modification.
This surveillance activity also includes any incidents or serious incidents defined by the MDR as:

- "*incident*": means any malfunction or deterioration in the characteristics or performance of a device made available on the market, including use-error due to ergonomic features, as well as any inadequacy in the information supplied by the manufacturer and any undesirable side-effect (art. 2(64) MDR)
- "*serious incident*": means any incident that directly or indirectly led, might have led or might lead to any of the following: a) the death of a patient, user or other person; b) the temporary or permanent serious deterioration of a patient's, user's or other person's state of health; c) a serious public health threat (art. 2(65) MDR).

Serious incidents must be reported to the manufacturer and, through EUDAMED, to the competent authority.
Non-serious incidents, on the other hand, do not have to be reported to the competent authority; they must, however, be documented and taken into account in the manufacturer's quality management system and reported in accordance with the requirements of Art. 88 MDR.
It follows, therefore, that upon the occurrence of both serious incidents and possible non-serious incidents to end users and their companions or to professional users in connection with the use of the device **it is mandatory to send** to **Pro Medicare** a copy of a fully completed "*Annex 2 - Reporting of after-sale incidents*". Pro Medicare S.r.l., as soon as it receives the aforementioned form, will provide the appropriate communications to the professional/end user, including the possible authorization to repair the damaged device or its replacement, also providing for the adoption of measures within its competence, appropriate to the nature and gravity of the incident detected.
In cases of particular urgency **it is mandatory** to contact the manufacturer at the following number **+39 0831 777840** sending to ***sales@promedicare.it*** the fully completed *Annex 2* as soon as possible.

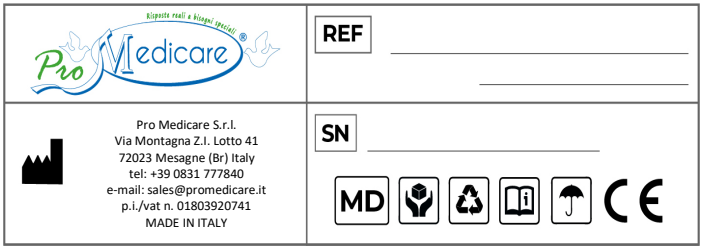
10. DISPOSAL/RECYCLING

Please, follow the local disposal and recycling regulations.
Following there is the description of all materials used (It is recommended to proceed with a separation of the different components of the Positioning System accessories):

- Aluminium: headrest hardware, various type of brackets, backrest shell
- Steel: screws, threaded inserts
- Wood: seat and backrest bases, calf support bases, support bases, hip guide bases, trays, abductor wedge bases
- Plastica: thoracic support bases, mounting inserts of the bases on wheelchair frame, packaging
- Synthetic fabric covers (polyester, elastane, etc.) and padding belonging to the polyethylene or polyurethane foam family
- Paper: cartoon or wrapping paper.

11. LABELING

The label is sticked on the second page of this manual. Product data are indicated on the label. In case of replacing parts orders and/or reports, the serial number of the product is duly requested. A facsimile of the label is shown below:



Manufacturer

MD Medical Device

Handle with care

Recovery/Recyclable

Consult Instruction for Use

Keep dry

CE Mark

SN Serial Number

REF Catalog Number

Annex A - "Technical features"

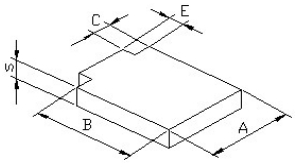
This annex describes the different sizes of the VERSA range devices. It is an integral part of the instruction manual. For further information please contact our Technical Sales Department at the following number:

+39 0831 777840

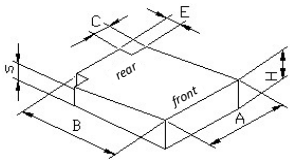
Generally the positioning system provided by Pro Medicare is composed of the seat and backrest which are available in various sizes and shapes to meet the required needs. The seat and backrest structures are made of polyethylene. The padding consists of layers of special polyurethane, "Memory Foam" coupled in different thicknesses and densities and provides exceptional softness and comfort. It is self-modeling and distributes the body weight over the entire surface decreasing the contact pressure in a decisive way.

The positioning system is supplied with lateral hip guides, thoracic supports, the abductor wedge or arm supports. These accessories can be positioned along the edges of the seat and backrest by means of appropriately shaped brackets. The brackets have slots to adjust the accessories attached to them so that the correct seating position can be determined. The elements of the positioning system are covered with a fireproof, anti-mite and hypoallergenic fabric. It can be supplied in different colors. Below are the relative measures.

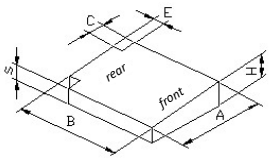
SEAT



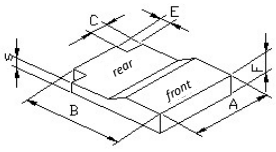
flat seat



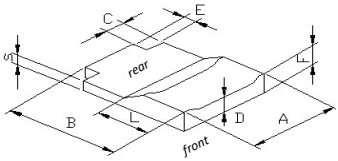
wedge seat
(anterior or posterior)



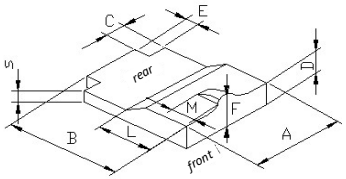
lateral wedge seat
(right or left)



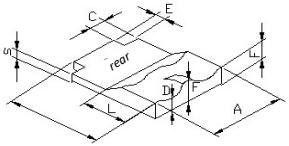
anti-thrust seat



anti-thrust seat with adductor



anti-thrust seat with abductor



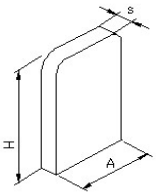
contoured seat

Measure (cm)	US	XXS	XS	XS1	S	M	M1	L	XL
A	30	36	36	39	42	42	45	48	48
B	38	38	42	44	44	50	50	44	50
L	16	16	18	19	19	24	24	19	24
M	10	11	12	13	13	15.5	15.5	13	15.5
D	9	9.5	9.5	9.5	12.5	12.5	12.5	12.5	12.5
F	13	14	14	14	17	17	17	17	17
S	6	6	6	6	8	8	8	8	8
H	8	8,5	8,5	11	11	12	12	11	12

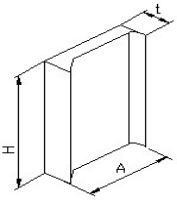
Common values for all seats:

C = 5 cm	E = 6 cm

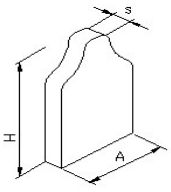
BACKREST



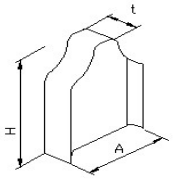
flat backrest



contoured backrest



flat backrest with scapular cuts-out



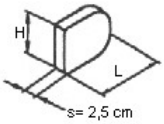
contoured backrest with scapular cuts-out

Measure (cm)	US	XXS	XS	XS1	S	M	M1	L
A	30	36	36	39	42	42	45	48
H	38	38	42	46	46	50	52	50

Common values for all backrest:

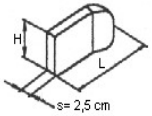
s = 5 cm	t = 8 cm

THORACIC SUPPORTS



flat thoracic support

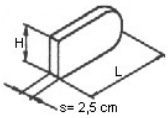
Measure (cm)	XS	S	M	L
H	8	10	12	12
L	10	12	15	18



contoured thoracic support

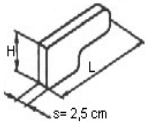
Measure (cm)	XS	S	M
H	8	10	12
L	14	16	19

LATERAL HIP GUIDES



linear hip guide

Measure (cm)	XS	S	M	L
H	8	10	10	12
L	22	25	30	35

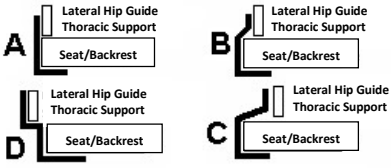


contoured hip guide

Measure (cm)	XS	S	M	L
H	8	10	10	12
L	22	25	30	35

BRACKETS

The shape of the brackets allow the adjustment of the seat and/or backrest width, in particular:



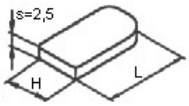
A. L / 90° Bracket allows a reduction of the width up to 2.5 cm per side
B. 2.5 cm Offset Bracket allows a reduction of the width up to 5 cm per side
C. 5 cm Offset Brackets allows a reduction of the width up to 7,5 cm per side
D. Reverse Bracket doesn't allow any variation of the width

Each brackets can be of different types:

1. Standard bracket (three leghts)
2. Detachable bracket (two lenghts)
3. Folding bracket

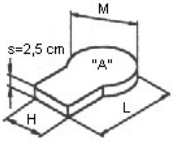
The brackets are mounted to the seat and backrest by means of screws that fit into the T-Nuts on the covered wooden bases.

ARM SUPPORTS



flat arm support

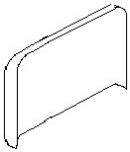
Measure (cm)	XS	S	M	L
H	8	10	10	12
L	22	25	30	35



flat and shake arm support

Measure (cm)	XS	S	M	L
H	8	10	10	12
L	30	35	40	48
M	12	15	17	17

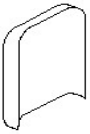
CALF SUPPORTS



Calf panel

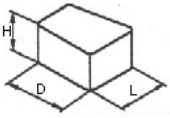
Measure (cm)	US	XXS-XS	XS1	S-M	M1	XL
A	23	26	29	32	35	38
B	12	12	15	18	18	18

Measure (cm)	US	XXS-XS	XS0-XS1	S-M	M1	L-XL
A	10	12	15	18	18	18
B	23	26,5	25	28	31	34



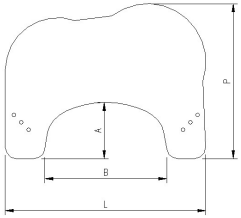
separate leg cradle

ABDUCTOR WEDGE



Measure (cm)	S	M	L
H	7.5	9	10
D	10	11	14
L	9	9,5	13

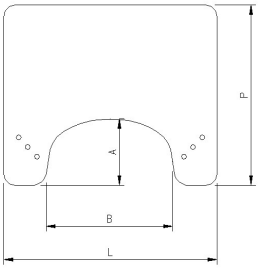
TRAYS



ergonomic tray

Measure (cm)	US	P	M	G
P	47	53	58	66
L	58	69	75	86
B	35	42	49	55
A	17	19	21	24

Measure (cm)	US	P	M	G
P	45	50	55	63
L	56	66	71	82
B	35	42	48	55
A	17	19	21	24



rectangular tray